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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,340	02/19/2002	Hidekazu Shodai	YAMZ 2 00009	3665
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Fay Sharpe LLP 1228 Euclid Avenue, 5th Floor The Halle Building Cleveland, OH 44115				
EXAMINER				
TRAN, SUSAN T				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/914,340

Applicant(s)

SHODAI ET AL.

Examiner

S. Tran

Art Unit

1615

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-8 and 10-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-8 and 10-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C2)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/17/09 has been entered.

Claim Rejections - 35 USC § 103

Claims 1, 7, 12-17, 19-24, 27-30 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. GB 2151201 A, in view of Monte US 5,578,336 and Brox US 4,780,316.

Ebert teaches a chewable soft gelatin capsule comprising confectionary fill material (abstract; and page 2, lines 40-47). The filled capsule is dried over a length of time until the desired chewing characteristics are attained (abstract; page 2, last paragraph; and examples). The capsule shell comprises gelatin, and plasticizer such as glycerin or sorbitol (page 1, last paragraph through page 2, paragraphs 1-5). The shell further comprises flavoring agent, and taste modifier (page 2, lines 33-35).

Ebert does not explicitly teach the claimed confectionary fill material.

Monte teaches a confectionary composition useful for the delivery of active agents, the composition comprising chocolate candy consisting mainly of roasted cacao

beans, cacao butter, and sugar (abstract; column 5, lines 66 through column 6, lines 1-9; and example 29). Monte further teaches active agents include vitamins, enzymes, phytochemicals, and alimentary vegetable compositions are incorporated in the confection core (column 5, lines 30-35; and example 29). Thus, it would have been obvious to one of ordinary skill in the art to modify the chewable soft capsule of Ebert to include the confectionary composition of Monte to obtain the claimed invention, because Monte teaches using chewable confectionary composition as a carrier for drugs, because Monte teaches chewable confectionary such as chocolate candy is known in pharmaceutical art, and because Ebert teaches the use of confectionary composition as a fill material suitable for the delivery of active agents.

It is noted that Ebert does not expressly teach the claimed drying temperature. However, absent of evidence to the contrary, the burden is shifted to applicant to show that Ebert does not teach dry the capsule under the claimed temperature. This is because Ebert teaches drying the soft gelatin capsule to obtain characteristics. It is noted that Ebert teaches an improved chewable soft gelatin capsule having the properties desired by the applicant, *e.g.*, normal chewing consistency over an extended period of time (page 1, lines 35-37), and avoidance of unpleasant taste (page 1, 2nd paragraph). However, to be more specific, Brox is cited for the teaching of storing (aging) soft gelatin capsule under temperature of 20°C, 30°C, and 40°C for one month to obtain a chewable capsule having suitable hardness (abstract; and column 5, lines 15-20). Therefore, it would have been obvious to one of ordinary skill in the art to age the soft capsule of Ebert at 30°C and 40°C in view of the teaching of Brox, because

Brox teaches that it is well known to store soft gelatin capsule under such temperature to achieve suitable capsule shell hardness, and because Ebert teaches the desirability to obtain soft gelatin capsule having improved characteristics.

Claims 1, 4-7, 11, 12, 15-17, 19-30 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. GB 2151201 A, in view of Cavanak US 5,639,724 and Brox US 4,780,316.

Ebert and Brox are relied upon for the reason stated above. Ebert does not explicitly teach the claimed filling material.

Cavanak teaches a confectionary composition comprising vegetable fats, and a drug such as cyclosporin (abstract; column 13, lines 7-26; and example 5). Vegetable fats include cacao fat, cacao butter, conventional chocolate bases, couverture chocolate, and mixtures thereof (ID). Example 5 discloses the claimed percent amounts of chocolate in the composition. Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule of Ebert to include the chocolate-cyclosporin candy in view of the teaching of Cavanak, because Cavanak teaches incorporating drug into chocolate base is known in pharmaceutical art, because Cavanak teaches a chocolate candy comprising cyclosporin to achieve acceptable taste (column 3, lines 41-45), and because Ebert teaches the use of confectionary as a fill material suitable for the delivery of a wide variety of drugs.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. GB 2151201 A, in view of Monte US 5,578,336 or Cavanak US 5,639,724, and Nishizawa et al. US 4,463,024.

Ebert in view of Monte or Cavanak are relied upon for the reasons stated above. Monte and Cavanak do not teach bitter chocolate.

Nishizawa teaches a flavoring composition comprising chocolate including bitter chocolate (example 18). Thus, it would have been obvious to one of ordinary skill in the art to include bitter chocolate to the chocolate composition of Monte or Cavanak to obtain the in view of the teaching of Nishizawa, because Nishizawa teaches using bitter chocolate from cacao bean to obtain a superior flavoring composition, because Monte and Cavanak teaches the use of chocolate including cacao bean.

Claims 1, 4-7, 11, 12, 15-17, 19, 20, 22, 24-30 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lech US 6,027,746, in view of Cavanak US 5,639,724.

Lech teaches a chewable soft gelatin capsule comprising a solid or liquid fill material (abstract; and column 2, lines 48-50). The fill material comprises flavors, sweeteners, and other food-grade excipient including oils and fats fillers (column 3, lines 1-4; and column 4, lines 66 through column 5, lines 1-17). Lech further teaches the filled capsule is stored at temperature 30°C, 40°C and 50°C for an extended period of time (aging) (column 7, lines 28-30).

Lech does not expressly teach the claimed fill material.

Cavanak teaches a confectionary composition comprising vegetable fats, and a drug such as cyclosporin (abstract; column 13, lines 7-26; and example 5). Vegetable fats include cacao fat, cacao butter, conventional chocolate bases, couverture chocolate, and mixtures thereof (ID). Example 5 discloses the claimed percent amounts of chocolate in the composition. Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule of Lech to include the chocolate-cyclosporin candy in view of the teaching of Cavanak, because Cavanak teaches it is well known in pharmaceutical art to use vegetable fat including chocolate base as a fill material for oral dosage form, (column 3, lines 41-45), and because Lech teaches the desirability to use fill materials comprise flavors, sweeteners, and fats to obtain a suitable oral dosage form.

Claims 8, 12-16 and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lech US 6,027,746, in view of Cavanak US 5,639,724 and Katsuragi et al. US 5,756,543.

Lech and Cavanak are relied upon for the reason stated above. Lech does not teach fats include lard, coconut oil, or polyethylene glycol.

Katsuragi teaches a bitterness-relieving agent comprising fats including vegetable and animal fats such as coconut oil, lard, and the like, and combination thereof (abstract; and column 4, lines 12-30). Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule fill of Lech to include coconut oil, lard, and polyethylene glycol as a fat in view of the teaching of Katsuragi, because Katsuragi teaches the use of these fats in a composition to mask the taste of bitter drugs, and

because Lech teaches the desirability to use fat as a fill material to obtain a suitable chewable capsule in which the bitter taste of drug has been masked.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lech in view of Mehta US 5,084,278.

Lech is relied upon for the reason stated above. Lech does not explicitly teach the flavoring agent such as chocolate flavor.

Mehta teaches a chewable taste mask capsule comprising a fill composition containing sweetening agent, and flavoring agent includes chocolate flavor (column 9, lines 46 through column 10, lines 1-15). Thus, it would have been obvious for one of ordinary skill in the art to include chocolate flavor in the fill material of Lech, because Mehta teaches the use chocolate flavor in chewable dosage form is preferable, and because Lech teaches the desirability to include a wide variety of flavors useful to obtain a chewable dosage form.

Response to Arguments

Applicant's arguments filed 06/17/09 have been fully considered but they are not persuasive.

Applicant argues that the Examiner's reasoning relied on references discussing storage for extended periods of time. Claims 1, 30, 36, and 37 have been amended to recite that the aging time has an upper limit of 64 hours. Support for this requirement can be found in the text running from page 36, line 17 to page 38, line 5 of the

specification. This distinguishes the present claims over the cited references, which had a minimum storage period of one month. This also responds to the Examiner's statement that the feature upon which applicant relies (i.e. that storage for several weeks would change the crystals into undesirable Type VI crystals) was not recited in the rejected claims.

However, in response to applicant's arguments *that the cited references had a minimum storage period of one month*, it is noted that Brox also teaches a storage condition at 0 month (see Table 2 at column 5). Further, absent of evident to the contrary, the burden is shifted to applicant to show that the teaching of Lech with respect to the storage condition "over an extended periods" in deed indicate a minimum storage period of one month as alleged by the applicant.

Applicant argues that the examples show that the claimed conditions are suitable for (i) forming Type V crystals and (ii) preventing the Type V crystals from changing into undesirable Type VI crystals. As to (i), Production Example 29 shows that cacao butter aged from 25-40°C for 16 hours is mainly Type V crystal. As to (ii), Production Example 30 shows that maximal hardness was obtained at 35°C after aging for 16 hours and that such hardness did not change up to 64 hours. As discussed on page 20 of the specification, Type VI crystals are harder than Type V crystals. Thus, the lack of change in hardness shows that Type VI crystals were not formed during the 64-hour period. Thus, the claimed subject matter is not obvious over the cited references. Applicants request withdrawal of the three 103(a) rejections.

However, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., forming Type V crystals and (ii) preventing the Type V crystals from changing into undesirable Type VI crystals; and Type VI crystals are harder than Type V crystals) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is further noted that the cited references teach the properties desired by the applicant, namely, Ebert teaches drying the soft gelatin capsule to obtain characteristics such as an improved chewable soft gelatin capsule having the properties desired by the applicant, e.g., normal chewing consistency over an extended period of time (page 1, lines 35-37), and avoidance of unpleasant taste (page 1, 2nd paragraph), Brox teaches an improved characteristics soft shell capsule, and Lech teaches a chewable capsule in which the bitter taste of drug has been masked.

Accordingly, the rejections of record are maintained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615